REMARKS

Applicants respectfully request consideration of the amendments to the specification and claims as herein presented. Pending claims 1-13 and 15-23, and 25-39 are herein amended. Claims 40-42 are withdrawn from consideration as non-elected inventions. Applicants reserve the right to file divisional applications claiming the subject matter of claims 24, and 40-42.

Applicants gratefully acknowledge Examiner Kathleen Kerr's interview of April 6, 2005. The substance of the discussion is summarized in the Interview Summary made of record in the present case. After carefully considering the objections and rejections raised in the Office Action mailed March 14, 2005, Applicants respectfully request reconsideration and early allowance of the amended claims herein presented.

Claim of Priority to Earlier Filed Co-pending Application

Applicants respectfully make a request for the benefit of priority of an earlier filed co-pending case under 35 U.S.C. §120 as set forth in 37 C.F.R. 1.78(a)(2)(ii), claiming the benefit of priority to the co-pending case U.S. Serial No. 09/722,441 (now allowed) filed on November 28, 2000, naming Paul D. Hanke, Lhing-Yew Li-D'Elia, and Holly J. Walsh as inventors. The earlier filed co-pending U.S. Serial No. 09/722,441 and the present case have one common inventor Lhing-Yew Li (formerly Lhing-Yew Li-D'Elia). Said U.S. Serial No. 09/722,441 claims the benefit of priority to U.S. Provisional Application No. 60/184,130 filed on February 22, 2000 and to U.S. Provisional Application No. 60/173,707 filed on December 30, 1999. The application to which a

claim of benefit of priority is co-pending as it has not been patented, abandoned, and proceedings have not been terminated in the application. Applicants gratefully acknowledge the notice of allowability of U.S. Serial No. 09/722,441 mailed on February 9, 2005 and note for the record that the issue fee had not been paid as of the filing of the paper on April 7, 2005, thus proceedings had not terminated on U.S. Serial No. 09/722,441 until the issue fee was timely paid on May 9, 2005. The provisions of 37 C.F.R. 1.78(a)(2)(ii) require that a claim of priority to an earlier filed co-pending application be made no later than the latter of 16 months from the filing of the earlier application, or four months from the filing of the later-filed application. However, the provisions of 37 C.F.R. 1.78 (3) state that if the reference required by 35 U.S.C. 120 and paragraph (a)(2) of this section is presented after the above-mentioned time periods, the claim under 35 U.S.C. 120, 121 or 365(c) for the benefit of a prior-filed copending nonprovisional application may be accepted via petition if the reference identifying the prior-filed application by application number and filing date was unintentionally delayed. Applicants enclose a copy of such a Peitition under Appendix B that is being mailed under separate cover to Mail Stop Petitions.

The amendments to the claims herein presented are summarized as follows:

Claim 1 has been amended to positively recite the elements of the polynucleotide of the invention to include nucleic acids encoding aspartate kinase (ask), aspartate semialdehyde dehydrogenase (asd), dihydrodipicolinate reductase (dapB), and diaminolpimelate dehydrogenase (ddh). By this amendment, the limitation excluding the polypeptides that convert L-piperidine-2,6-dicarboxylate to D,L-diaminopimelate is rendered unnecessary and it is stricken. Support for this amendment is found in the specification as filed and thus no new matter is introduced.

Claim 2 has been amended to reflect language that properly depends from amended claim 1.

Claim 3 has been amended to remove the activity of the ORF2 polypeptide as this was deemed to be new matter though suggested by the Examiner during the interview of October 21, 2004. As discussed *infra*, the recited activities are a feature of the ORF2 polypeptide and not new matter. Thus, the present amendment is related to form and not substance and does not alter the scope of the claim because the recited activities are inherent to ORF2. Claim 3 is amended to clearly define the bounds and to clearly point out and distinctly claim Applicants' invention.

Claim 4 has been amended to clearly point out and distinctly claim the subject matter of Applicants' invention. The formatting of the claim has been amended.

The remaining amendments will be noted as they correspond to overcome specific objections and rejections as set forth below.

The following are the items presented in the Office Action of March 14, 2005 and listed numerically.

1. Applicants gratefully acknowledge the removal of the finality of the office action pending in the previous case and entry of the instant application on December 7, 2004.

2. Applicants gratefully acknowledge the pendency of claims 1-13, 15-23 and 25-39 in the instant application.

3.- 6. Applicants respectfully traverse the restriction of the pending claims as proposed, as all of the subject matter of the claims are inextricably entwined as a process for making lysine, materials for making lysine, and lysine produced by the materials used in the process of making

lysine of Applicant's invention. Thus, Applicants respectfully traverse the restriction of their invention into Groups I, II, III, IV and V and respectfully submit that it is not unduly burdensome to search the components of Groups III, IV and V, which have already been disclosed in Groups I and II. Nevertheless, Applicants respectfully preserve the right to file divisional applications directed to the non-elected Groups during the pendency of the instant case.

7. Applicants gratefully acknowledge the grant of priority of the instant application to Applicants Provisional Application No. 60/267,183 filed on February 8, 2001, with respect to claim 13. Applicants respectfully point out that the previous response with the Request for Continued Examination filed on December 7, 2004 was filed in reliance upon the substance of the interview with Examiner Kerr of October 21st, 2004 and made of record in the parent case. Said response was Applicants' and their Attorneys' understanding of the agreement reached during that interview that the pending claims as proposed to be amended were supported in Applicants' Provisional Application filed on February 8, 2001. During such discussion no mention was made that such support was limited to Claim 13. Nevertheless, Claim 1 is presently herein amended to positively recite a nucleic acid comprising a diaminopimelate dehydrogenase. As conceded by the Office Action of March 14, 2005 support for the limitation of nucleic acids comprising diaminopimelate dehydrogenase in addition to aspartate kinase, aspartate semialdehyde dehydrogenase, and dihydrodipicolinate reductase is found in the Provisional Application 60/267,183 filed on February 8, 2001. Thus all depending claims 3-8, 10-12, 15-23, and 25-28 recite the limitation of a nucleic acid comprising a diaminopimelate dehydrogenase. As such all pending claims in the instant application are entitled to the benefit of priority to Provisional Application 60/267,183 and so Applicants respectfully request that the right of

priority to Provisional Application 60/267,183 be acknowledged for the record. The following were asserted in the office action of March 14, 2005 and are herein addressed.

a) The limitation in claim 2 with respect to 80% identity to polypeptides *is* supported in the specification in both the provisional application and the instant specification. See for example paragraph [0056] of the provisional application or paragraphs [0074] or [0075] of publication US 2003/0055232 A1 corresponding to the instant specification of the present Application.

b) As herein amended claims 3-8, 10-12, 15-23, and 25-38 depending from claim 1 now recite the diaminopimelate dehydrogenase or ddh or H limitation expressly.

c) Claim 9 recites diaminopimelate dehydrogenase or ddh "polypeptide encoded by a gene from a cell of the genus *Corynebacterium*." Thus, the statement made in the Office Action that "Claim 9 does not require the ddh as found in the provisional" is wrong.

d) Claim 39 has support in Applicants' disclosure in paragraph[0054] of Published Application US 2003/0055232A1, and in U.S. Provisional Application Serial No. 60/267,183 disclosing a preferred embodiment of the KDB genus.

e) As noted *supra*, Applicants gratefully acknowledge the grant of priority of the instant application to Applicants' Provisional Application No. 60/267,183 filed on February 8, 2001, with respect to claim 13.

8. Applicants gratefully acknowledge the withdrawal of the previous rejection of claim 20 under 35 U.S.C. § 112, second paragraph, as being indefinite, by virtue of Applicants' amendment previously entered.

9. Applicants respectfully submit that the rejection of claim 25 under 35 U.S.C. § 112, second paragraph, for the term "N-succinylaminoketopimelate transaminase (dapC)" is without sound basis. The standard for definiteness is what a person having ordinary skill in the art to which the invention belongs would understand by the term "N-succinylaminoketopimelate transaminase (dapC)." The person of skill in the art recognizes that enzymatic reactions are reversible and, accordingly, that there is more than one nomenclature approach to naming a given enzyme with a defined enzymatic activity. The enzyme can be named from the perspective of the "substrate to product" nomenclature approach or from the "product from substrate" nomenclature approach. Thus, the two allegedly "ambiguous activities" of N-succinylaminoketopimelate transaminase (dapC) only reflect these two approaches to enzyme nomenclature. Applicants respectfully point out that the terms aminotransferase and transaminase are used interchangeably by a person of skill in the art. Applicants further point out that in organic chemistry nomenclature there are more than one acceptable nomenclature for the same compound that nonetheless identify the same structural compound. The activity of N-succinylaminoketopimelate transaminase (dapC) is as depicted in Figure 1 which catalyzes the trans-amination of N-succinyl-2-amino-6-ketopimelate to N-succinyl-2,6-L,L-diaminopimelate. Thus, the activity of dapC is consistent and definite to a person of skill in the art, but the nomenclature may reflect the "substrate to product" and the "product form substrate" approaches to nomenclature both of which are definite and have a clear meaning to said person of skill in the art to which this invention belongs.

Thus, Applicants having fulfilled the requirement to particularly point out and distinctly describe their invention to a person of ordinary skill in the art, Applicants respectfully request that the rejection of claim 25 under 35 U.S.C. § 112, second paragraph, be withdrawn.

10. Applicants gratefully acknowledge the withdrawal of claim rejections under 35 U.S.C. §112, first paragraph, and address *infra* any remaining rejections thereunder.

11. The rejection of claims 7, 9-11, and 26-29 under 35 U.S.C. § 112, paragraph 1 originally made to the language "native to...*Corynebacterium*" was maintained to the as-amended language "from a cell of the genus *Corynebacterium*" which amendment was made with the understanding that this was acceptable following the interview with Examiner Kerr on October 21, 2004. It is axiomatic that unless otherwise defined by the inventor who can be his or her own lexicographer, the plain meaning of words are to be ascribed to words in the specification and claims. Applicants submit that either "native to" and "from a cell" of the genus *Corynebacterium*, when properly given their plain meaning are synonymous and particularly point out and distinctly claim the subject matter that Applicants regard as their invention. With the foregoing explanation of the plain meaning of the phrases "native to" and "derived from", Applicants respectfully submit that they have particularly described and pointed out and distinctly claim their invention, and respectfully request the rejection of claims 7, 9-11, and 26-29 under 35 U.S.C. § 112, paragraph 1, be withdrawn.

The Office Action of March 14, 2005 states regarding the instant specification "Clearly, ask, ddh, ORF2, and lysA sequences from coryneform (sic) within the structural limitations are enabled by the disclosure." Thus, this cannot be the basis of a proper rejection of Applicants invention with the limitation of a gene "derived from" or "native to" *Corynebacterium*. Applicants respectfully submit that instant specification particularly describes, points out and distinctly claim their invention given the plain meaning of "from a cell of the genus *Corynebacterium*". Thus, given that an *E. coli* cell is not a cell of the genus *Corynebacterium,* it

cannot be the basis for interpreting the claim language which clearly excludes it. Thus given the accepted standard of examination which requires that unless otherwise defined language in claims be given its plain language meaning, Applicants respectfully request the rejection of claims 7, 9-11, and 26-29 under 35 U.S.C. § 112, paragraph 1, be withdrawn.

12. Applicants gratefully acknowledge the withdrawal of the previous rejection of claim 13 under 35 U.S.C. §102(a) as being allegedly anticipated by Li *et al.* (WO 01/49854) since claim 13 is granted priority to February 8, 2001 making this reference not available as prior art.

13. Applicants gratefully acknowledge the withdrawal of the previous rejection of claims 3, 5, 6, and 10 under 35 U.S.C. § 102(a) as being allegedly anticipated by Li *et al.* (WO 01/49854).

14. Applicants gratefully acknowledge withdrawal of the provisional rejection of claims 3 and 10 under 35 U.S.C. § 102(e) as being anticipated by Hanke *et al.* (U.S. Application 09/722,441 now allowed).

15. Claims 1, 2, 4, 7-9, 11-12, 15-23, 25-38 were previously rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by Hanke *et al.* (WO 01/49854, published July 12, 2001). Applicants restate their argument that this reference is not available as prior art under §102(a) because it was published on July 12, 2001 and Applicants herein request the grant of priority to Provisional Application 60/267,183 filed on February 8, 2001, as the claims as herein amended have support in Provisional Application 60/267,183. Therefore Hanke *et al.* WO 01/49854 is not available as prior art with a publication date of July 12, 2001 versus the filing date of U.S. Provisional Application 60/267,183 on February 8, 2001 to which priority date Applicants are entitled.

Furthermore, on April 7, 2005 Applicants have filed a Petition for claim of priority being treated by the Office of Petitions under 37 C.F.R. 1.78 (a)(3) to accept an unintentionally delayed

claim under 35 U.S.C. 120 and 119(e). Therefore, upon the granting of the Applicants' Petition, for the benefit of priority to U.S. Application Serial No. 09/722,441, the Hanke *et al.* reference is not available as prior art. Applicants have attached under Appendix B hereto a copy of Applicants' Renewed Petition in response to the Office of Petitions communication dated June 1, 2005. For these reasons, Applicants respectfully request that the rejection of claims 1, 2, 4, 7-9, 11-12, 15-23, 25-38 under 35 U.S.C. § 102(a) in view of Hanke *et al.* be withdrawn.

16. Claims 1, 2, 4, 7-9, 11-13, 15-23, 25-38 (adding claim 13 to the previous rejection) were rejected under 35 U.S.C. § 102(e) in view of Hanke *et al.* (WO 01/49854, published July 12, 2001). As discussed *supra* in paragraph 15 and herein, Applicants herein request the right of priority to Provisional Application 60/267,183 (see Petition, Appendix B) as the claims as herein amended have support in the Provisional Application 60/267,183 filed on February 8, 2001 before the publication date of Hanke *et al.* (WO 01/49854). Thus, the Hanke *et al.* reference is not available as prior art with a publication date of July 12, 2001 versus the filing date of U.S. Provisional Application 60/267,183 on February 8, 2001 to which priority date Applicants are entitled.

Furthermore, Applicants' Petition (see Appendix B) requests the benefit of priority as a continuation application of the Hanke *et al.* reference 09/722,441 (now allowed) having at least one common inventor. Therefore, upon the granting of the benefit of priority to the Hanke *et al.* reference 09/722,441, this reference is not available as prior art. For these reasons, Applicants respectfully request that the rejection of claims 1, 2, 4, 7-9, 11-13, 15-23, 25-38 under 35 U.S.C. § 102(a) in view of Hanke *et al.* be withdrawn.

17. Applicants' amendment of claims 4, 41 and 42 of December 7, 2004 was rejected as allegedly adding new matter to the disclosure. Applicants previously amended claims 4, 41 and

42 with the function of ORF2 "thymidilate synthase or 2,3-dihydrodipicolinate N-C6-lyase activity" in response to the Examiner's previous rejection under 35 U.S.C. § 112, first paragraph, as lacking functional language limitations. It is incorrect to assume that the structural limitation "at least 80% identity" to polypeptides, and "at least 95% identity" to polynucleotides is to be read to assume a lack of ORF2 function of those structurally defined species. Such assumption cannot be properly made unless expressly written in the claim language, which is clearly not the case with the instant claims. Applicants traverse the characterization of the function of ORF2 as new matter. Applicants' disclosure characterizes the function of ORF2 as increasing the synthesis of lysine in a cell of the genus *Corynebacterium* (see Example 2). It is well known by a person of ordinary skill in the art that the function of an enzyme is an integral and inherent property of its structure which has been adequately disclosed by its amino acid polypeptide sequence in SEQ ID NO:10 as expressed by the polynucleotide sequence of SEQ ID NO:9. The activity of thymidilate synthase or 2,3-dihydrodipicolinate N-C6-lyase is an inherent feature of the polypeptide of ORF2, and thus Applicants' previous amendment to recite that activity did not add new matter to the claim. In addition, a person of ordinary skill in the art given the structure as determined by its polypeptide sequence as expressed from a polynucleotide sequence can determine the activity of said protein without undue experimentation. Furthermore, the 80% identity to the polypeptide sequence and 95% identity to the polynucleotide sequence can be easily determined by a person of skill in the art using methods well known in the art to generate these variants. The scope of the claims thus is defined as those species of polypeptides that have 80% identity to SEQ ID NO:10 and polynucleotides that have 95% sequence identity to SEQ ID NO:9 which species have the function of ORF2. Thus applicants have adequately pointed out and distinctly claimed the subject matter of their invention having fully described at least one

species of ORF2 by polypeptide and polynucleotide sequence structure, have identified the common characteristics by at least 80% homology to the polypeptide of SEQ ID NO:10 and by at least 95% homology to the polynucleotide of SEQ ID NO:9, having the functional characteristic of ORF2 which is disclosed as increasing lysine production in cells from the genus *Corynebacterium* by Applicants' disclosure.

Thus, Applicants respectfully submit that the function of ORF2 is not new matter as it is inherent in the adequately described ORF2 polypeptide of SEQ ID NO:10 and polynucleotide of SEQ ID NO:9. Nevertheless, the named function "thymidilate synthase or 2,3-dihydrodipicolinate N-C6-lyase activity" is removed from the pending claims to expedite prosecution of the pending claims. Applicants emphasize, however, that this amendment does not alter the scope of the claim to the extent the ORF2 presently claimed (and disclosed in the Application) would inherently possess such activity.

18. Claim 4 is objected for use of the plural "polypeptides". Claim 4 as herein amended renders this objection moot.

19. Claims 17-19 are objected to for having inconsistent antecedent language. Claims 17-19 are herein amended to overcome these rejections.

20. Claim 30 was objected to for the comma after the first item in a Markush group of 2 items. Claim 30 is herein amended to overcome this rejection and Applicants respectfully request this rejection be withdrawn.

21. Claims 1-13, 15-24 (sic), and 26-38 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for use of the term "N-succinylaminoketopimelate transaminase (dapC)" in claim 1. Applicants respectfully point out that claim 24 has been withdrawn from consideration, thus the rejection should be of claims 1-13, 15-23 and 26-38 as addressed below.

Applicants respectfully submit that the rejection of claims 1-13, 15-23, and 26-38 under 35 U.S.C. § 112, second paragraph, for the term "N-succinylaminoketopimelate transaminase (dapC)" is without sound basis. The standard for definiteness is what a person having ordinary skill in the art to which the invention belongs would understand by the term "N-succinylaminoketopimelate transaminase (dapC)." The person of skill in the art would appreciate that there are more than one nomenclature approach to naming a given enzyme with a defined enzymatic activity. The enzyme can be named from the perspective of the "substrate to product" nomenclature approach or from the "product from substrate" nomenclature approach. Thus, the two allegedly "ambiguous activities" of N-succinylaminoketopimelate transaminase (dapC) only reflect these two approaches to enzyme nomenclature. Applicants respectfully point out that the terms "aminotransferase" and "transaminase" are used interchangeably by a person of skill in the art. Applicants further point out that in organic chemistry nomenclature there are more than one acceptable nomenclature for the same compound that nonetheless identify the same structural compound. The activity of N-succinylaminoketopimelate transaminase (dapC) is as depicted in Figure 1 which catalyzes the trans-amination of N-succinyl-2-amino-6-ketopimelate to N-succinyl-2,6-L,L-diaminopimelate. Thus, the activity of dapC is consistent and definite to a person of skill in the art, but the nomenclature may reflect the "substrate to product" and the "product form substrate" approaches to nomenclature both of which are definite and have a clear meaning to said person of skill in the art to which this invention belongs.

Thus, Applicants having clarified the meaning of the term "N-succinylaminoketopimelate transaminase (dapC)" have fulfilled the requirement to particularly point out and distinctly describe their invention to a person of ordinary skill in the art. Applicants respectfully request

that the rejection of claims 1-13, 15-23, and 26-38 under 35 U.S.C. § 112, second paragraph, be withdrawn.

22. Claims 4-6, 11, 15, 29 and 30 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for use of the language "optionally...optionally...and". Claim 4 from which claims 5, 6, 11, 15, 29 and 30 directly or indirectly depend has been herein amended as suggested by the Examiner, and Applicants respectfully request this rejection be withdrawn.

23. Claims 5-6 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for use of the phrase "comprises **a** P1 promoter element of SEQ ID NO:15" *(emphasis added)*. Applicants respectfully point out the plain language meaning of the phrase "a P1 promoter element of SEQ ID NO:15" in the claim and as described in the specification makes it clear that in order to be within the scope of the claim the P1 promoter element must have the nucleotide sequences from SEQ ID NO:15 that function as a "promoter." The term "promoter" is an established functional term for a nucleotide sequence that promotes initiation of transcription with an RNA polymerase. In the case of bacterial promoters, the minimally required nucleotide sequences for promoter function are well characterized and readily identified (e.g. consensus sequences in the -35 and -10 regions). The claims are to be given their plain language interpretation as understood by one of ordinary skill in the art or as defined in the specification. The specification clearly sets forth the language "P1 promoter element" which one of ordinary skill would interpret as sequences from within SEQ ID NO:15 that promote transcription. Applicants submit that the language of the claim indicates the use of any portion of SEQ ID NO: 15 that functions as a promoter. Thus, Applicants submit that the claim language as is clear and unambiguous given their description in the specification of a P1 promoter element of SEQ ID NO:15. Thus, Applicants respectfully request that this rejection be withdrawn.

24. Claims 7, 9-11, and 26-30 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for use of the phrase "from a cell of the genus *Corynebacterium.*" As stated *supra*, it is axiomatic that unless otherwise defined by the inventor who can be his or her own lexicographer, the plain meaning of words are to be ascribed to words in the specification and claims. Applicants submit that either "native to" and "from a cell" of the genus *Corynebacterium*, when properly given their plain meaning are synonymous and particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Applicants disclosure is devoid of any mention whatsoever of the introduction of the genes of the invention from a cell other than a cell of the genus *Corynebacterium,* thus the Examiner's interpretation that "the gene could be a gene introduced into *Corynebacterium"* is without basis in Applicants' disclosure. With the foregoing clarification of the plain meaning of the phrases "native to" and "derived from", Applicants respectfully submit that they have particularly described and pointed out and distinctly claimed their invention, and respectfully request the rejection of claims 7, 9-11, and 26-30 under 35 U.S.C. § 112, paragraph 1, be withdrawn.

25. Claims 26-30 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for use of the term "bacterium." Applicants respectfully point out that their invention is directed to *bacterial* host cells and *bacterial* genes to produce lysine in *bacteria* particularly of the genus *Corynebacterium*, thus the statement that claims 7, 9-11 do not have "anything to do with a generic bacteria" is wholly without basis. Nevertheless, Applicants amend claims 26 -30 to reflect proper antecedent basis and respectfully request this rejection be withdrawn.

26. Claim 37 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for use of the phrase "said vector". Claim 37 is amended as suggested by the Examiner, thus maiking this rejection moot.

27. Claims 2-6, 8-11 and 27-30 were rejected under 35 U.S.C. 112, second paragraph, for allegedly introducing new matter for the limitation "at least 80% identity to SEQ ID NO:8 or 12 or 2 or 4." Applicants respectfully quote from paragraph [0054] of the corresponding U.S. published application US 2003/0055232 A1, which states in relevant part:

> "[0054] In another embodiment, the KDB polynucleotide molecule consists essentially of a nucleic acid molecule encoding an ask polypeptide, a nucleic acid encoding an asd polypeptide, and a nucleic acid molecule encoding a dapB polypeptide."

Thus, the disclosure expressly describes KDB polypetides as the product of expression of a KDB polynucleotide of the invention. The disclosure goes on to state in paragraph [0075] of the same publication how the 80% homology to SEQ ID NO:6 or 12 or 2 or 4 can be determined:

> "[0075] As a practical matter, whether any particular polypeptide is at least 80%, 85%, 90%, 92%, 95%, 96%, 97%, 98%, or 99% identical to, for instance, the amino acid sequence shown in SEQ ID NO:2, 4, 6, 8, 10, 12, 14 or to the amino acid sequence encoded by a nucleic acid sequence can be determined conventionally using known computer programs [...]."

Thus, the limit of 80% homology to polypeptides of SEQ ID NO:6 or 12 or 2 or 4 (dap(B), lysA(A), ask(K), and asd(D)) is indeed supported in the specification as filed in paragraphs [0054] and [0075] of Applicant's application publication US 2003/0055232 A1. Applicants request the withdrawal of the new matter rejection as they have shown that there is support for the "at least 80% identity" limitation in the application as originally filed.

28. Claims 2-6, 10, 11, 15, 28, 29, and 30 were rejected under 35 U.S.C. §112, first paragraph, for allegedly introducing new matter. As discussed *supra*, the function of ORF2 is

described as increasing lysine production in a bacteria of the genus *Corynebacterium*. The activity of ORF2 is inherent in its description given its structure as described by its polynucleotide and amino acid sequence disclosed in Applicants disclosure. Nevertheless, claims 3 and 4 have been amended to remove "thymidilate synthase or 2,3 dihydrodipicolinate N-C6-lyase activity." Thus Applicants respectfully request this rejection be withdrawn.

29. Claim 25 was rejected under 35 U.S.C. § 112, first paragraph, for allegedly having new matter. Applicants respectfully quote from paragraph [0059] of Applicants published application US 2003/00055232 A1:

> "[0059] In a preferred embodiment, the polynucleotide molecules of the present invention do not comprise any nucleic acid molecules encoding any lysine pathway polypetides other than ask, asd, dapB, ddh, ORF2, and lysA."

The language of claim 25, as amended, is the equivalent of paragraph [0059] which describes the polypeptides of Applicants' invention from among the lysine biosynthesis genes as described in Figure 1 ("the right hand pathway") and Claim 25 excludes the lysine biosynthesis pathway genes outside the scope of Applicants' instant invention ("the left hand pathway") of lysine biosynthesis pathway genes. Thus, claim 25 having support in the application as filed, no new matter is being introduced and Applicants respectfully request withdrawal of this rejection.

30. Claims 2-6, 9-11, 13, 15, 27-29, and 30 were rejected under 35 U.S.C. § 112, first paragraph, for use of the phrase "complete or truncated ddh polypeptide having at least 80% sequence identity with SEQ ID NO: 8." Applicants submit as discussed *supra* that the language "complete or truncated ddh polypeptide having at least 80% identity with SEQ ID NO.8" complies with the requirement that they specifically point out and particularly described their invention. The requirement that they "(1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict

the structure of other species encompassed by the claimed genus" is met by Applicants description of a ddh polypeptide of SEQ ID NO:8 to which the function of diaminopimelate dehydrogenase is described in paragraph [0063] of publication US 2003/00055232A1. The second requirement that they "(2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these" is met by the functional limitation that those polypeptides that are 80% identical to SEQ ID NO:8 have ddh activity. Applicants point out that it is incorrect to assume that a truncation of SEQ ID NO: 8 has a function other than ddh and is within the scope of the claims. It is well settled that a disclosure need not teach and preferably omits what is well known in the art to which the invention belongs. Nonetheless, Applicants disclose in paragraph [0076] of US Publication 2003/0055232 A1 the method of constructing polypeptides having ddh that are 80% identical to SEQ ID NO:8, by methods that are well known in the art to which their invention pertains.

Thus, Applicants having defined the scope of their invention by the limitation of "complete or truncated ddh polypeptide having at least 80% sequence identity with SEQ ID NO: 8" and respectfully request that the rejection of claims 2-6, 9-11, 13, 15, 27-29, and 30 under 35 U.S.C. § 112, first paragraph, be withdrawn.

32. Claims 3-6, 10, 11, 15, 28-30 were rejected under 35 U.S.C. § 112, first paragraph, written description, for use of the language "truncated ORF2 polypeptide encoded by a polynucleotide having at least 90% identity with SEQ ID NO:9 and at least 25% of the full length of ORF2." As noted *supra*, the assumption that the truncated ORF2 polypeptide not have ORF2 activity is incorrect. The ORF2 truncations and variants that have at least 90% identity, and are at least 25% of the full length of ORF2 and must have ORF2 function of increasing lysine

production. Thus, Applicants' claims have a functional limitation, and Applicants respectfully request the rejection of claims 3-6, 10, 11, 15, 28-30 under 35 U.S.C. § 112, first paragraph, be withdrawn.

33. Claims 34-36, and 39 were rejected under 35 U.S.C. § 112, first paragraph were rejected as not having an enabling deposit. Applicants have amended the specification to provide the requisite deposit information and provide herewith the requisite statement pursuant to MPEP § 2404.01certifying that all restrictions on accessibility to said deposits are irrevocably removed upon the granting of the patent. Thus Applicants respectfully request that the rejection of claims 34-36 and 39 under 35 U.S.C. § 112, first paragraph, enabling deposit be withdrawn.

Applicants respectfully point out that the requisite deposit information for NRRL-B30410 of claim 34 is listed in paragraph [0138] of US 2003/0055232A1; NRRL-30458 of claim 34 is listed in paragraph [0129] of US 2003/0055232A1; NRRL-B30459 of claim 34 is listed in paragraph [0153]of US 2003/0055232A1; and NRRL-B30522 of claim 34 is listed in paragraph [0168] of US 2003/0055232A1.

CONCLUSION

It is respectfully submitted that Applicants' Claims 1-13,15-23, and 25-39 as herein amended illustrate patentable compositions to produce L-Lysine in host cells that are not taught or suggested in the art of record. Applicants respectfully submit that the amendments and remarks set forth in this paper place this Application in condition for allowance and such action is courteously requested at an early date. Prompt and favorable consideration of this Response and Amendment is respectfully requested.

AUTHORIZATION

The Commissioner is hereby authorized to charge any necessary additional fees associated with this paper to Deposit Account No. 02-4553. A duplicate copy of this Response and Amendment is enclosed for deposit account purposes.

Respectfully submitted,

Buchanan Ingersoll PC

Dated: June 14, 2005

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